GOVERNMENT OF HIMACHAL PRADESH
STATE DRUGS CONTROLLER,
-CUM-LICENSING AUTHORITY
BADDI, DISTT. SOLAN (H.P.)
CERTIFICATE OF PHARMACEUTICAL PRODUCTS [1]

No. of Certificate : HFW-H[Drugs]231/05 (Vol- XII)/21-627
Valid up to: 13-04-2024

Exporting (certifying) Country : INDIA
Importing (requesting) Country : MENTIONED OVERLEAF

1.Proprietary Name (If applicable) and Dosage form of Product : **VEN-FLURO**
Fluorouracil Solution for Injection or Infusion
250mg/5 ml

1.1Active Ingredient(s)[2] and Amount(s) per unit dose[3]

Each ml contains:
Fluorouracil USP .. .. 50 mg
Water for Injection USP ..... . q.s

(For complete qualitative composition including excipients are not attached [4])

1.2 Is this product licensed to be placed on the market for use in the exporting country?
Yes ☒ No ☐ Not applicable ☐

1.3 Is this product naturally on the market in the exporting country? [5] Yes ☒ No ☐ Unknown ☐

(If the answer to 1.3 is Yes, continue with question 2.A and omit question 2.B) (If the answer to 1.3 is No, omit section 2.A and continue with section 2.B) [6]

2.A

1. Product license[7] and Date of issue:
MB/05/204,23-04-2021
2. Product-license holder: (Name & Address)
M/s. Venus Remedies Limited,
Hill Top Industrial Estate, Jharmajri, EPIP Phase-I (Extn), Bhatoli Kalan, Baddi, Distt. Solan, Himachal Pradesh,173205, India
3. Status of applicant: a/b/c (key in appropriate category as defined in note[8])
a ☒ b ☐ c ☐ [9]
4. Is an approved technical summary appended?[10]
Yes ☐ No ☒ Not Provided ☐
5. Is the attached, officially approved product information complete and consonant with the license?[11]
Yes ☐ No ☐ Not provided ☒
6. Applicant for certificate, if different from the License holder (Name & Address)[12] : **Not Applicable**

2.B

1. Applicant for Certificate : (Name & Address)
2. Status of Applicant: a/b/c (key in appropriate category as define in note [8])
a ☐ b ☐ c ☐
3. Why is authorization lacking?
Not Required ☐
Not Requested ☐
Under Consideration ☐
Refused ☐
4. Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced?[14] Yes ☒ No ☐ Not Applicable ☐ (if No or Not Applicable, Proceed to Question 4)

3.1 Periodicity of routine inspection: **ONCE IN A YEAR**

3.2 Has the manufacturer of this type of dosage form been inspected? Yes ☒ No ☐

3.3 Do the facilities and operations conforms to GMP as recommended By the World Health Organization? [15]
Yes / No/ Not applicable [14] Yes ☒ No ☐ Not Applicable ☐

4. Does the information submitted by the applicant satisfy the certifying Authority on all aspects of the manufacturer of the product?[16] Yes ☒ No ☐ If no, Explain.

Address of Certifying Authority :

STATE DRUGS CONTROLLER
Controlling-cum-Licensing Authority ,
BADDI, DISTT. SOLAN (H.P.)- 173205
01795-244288, sdc4 hp@gmail.com

Licensing Authority cum Drug Controller * Himachal Pradesh *

Name of Authorizing person
Signature

(NAVNEET MARWAHA)
(Navneet Marwaha)
Stamp & Date:
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H. P.)-173205
12 AUG 2021

THIS CERTIFICATE CONFORMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANISATION
(GENERAL INSTRUCTION AND EXPLANATORY NOTES ARE ON OVERLEAF)

Digitally signed by Chirtoacă Iurie
Date: 2021.09.10 08:41:05 MSK
Reason: MoldSign Signature
Location: Moldova

IMPORTING (Requesting) COUNTRY: **Congo, Costa Rica, C'ote d'hoiree fiodtia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Democratic Republic of the Denmark, Dominica, Dominica Republic Ecuador, Egypt, El Salvador, Equatorial Guinea, Estonia,Ethiopia Finland, France, Gabon, Gambia, Georgia, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Mali, Malta, Mauritania, Mauritius, Mexico, Monaco, Mongolia, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Syrian Arab Republic, Tajikistan, The former Yugoslav, Republic of Macedonia, Togo, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Uganda, Ukraine, United Arab Emirates, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Uzbekistan, Venezuela, Vietnam, Yugoslavia, Zambia, Zimbabwe**

Albania, Algeria, Antigua and Barbuda, Argentina, Armenia, Austria, Australia, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Central African Republic, Chad, Chile, China, Colombia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea Bissau, Guinea, Guyana, Haiti, Holy See, Honduras, Hungary, Iceland, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Lao People's Democratic, Latvia, Lebanon, Lesotho, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent & the Grenadines, San Marino, Sao Tome and Principe, Senegal, Sierra Leone, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Yemen.

GENERAL INSTRUCTION: Please refer to the guidelines for full Instructions how to complete with form and information on the implementation of the scheme. The forms are suitable for generation by computers. They should always be submitted as hard copy with responses printed in type rather than handwritten additional sheets should be appended, as necessary, to accommodate remarks and explanations.

EXPLANATORY NOTES

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country, it is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use whenever possible International Non-proprietary Names (INN's) or National Non-proprietary Names.
3. The formula (complete composition) of the dosage form should be given on the certificate to be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.
5. When applicable append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.
6. Section 2.A and 2.B are mutually exclusive.
7. Indicate, when application, if the license is provisional, or the product has not been approved.
8. Specify whether the person responsible for placing the product on the market:
   a) manufactures the finished dosage form;
   b) packages and/ or labels a dosage form manufactured by an independent company; or
   c) is involved in none of the above.
9. This information can be provided only with the consent of the product-license holder, or in the case of non-registered products. The applicant non-completion of this section indicates that the party concerned has not agreed to inclusion of the information. It should be noted that information concerning the site of production is part of the product license. If the production site has changed, the license must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities that summarizes the technical basis on which the product has been licensed.
11. This refers to the product information approved by the competent national regulatory authority such as a Summary of Product Characteristics (SPO).
12. In this circumstances, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason the applicant has provided for non-requesting registration:
    a) the product has been developed exclusively for the treatment of conditions-particularly topical diseases-not endemic in the country of export.
    b) The product has been reformulated with a view to importing its stability under tropical conditions.
    c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e) Any other reason, please specify.
14. Non applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the country of manufacturer.
15. The requirement for good practices in the manufacture and quality control of drugs referred to in the certificates ate those included in the thirty- second report of the expert committee on specifications for pharmaceutical, preparation (WHO technical report series, No;823, 1992, Annex.1). recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822, 1992, Annex. 1)
16. This section is to be completed when the product license holder or applicant conforms to status b) or c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product in these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

U-11-21-24-627

Date 12-08-21